Zai Lab Presents Results of its Pharmacokinetics (PK) Study for ZL-2306 (niraparib) in Chinese Ovarian Cancer Patients Showing Comparable Profile to non-Chinese Patients at the 21st Annual Meeting of the Chinese Society of Clinical Oncology

2018年 9月 26日

SHANGHAI, China, Sept. 26, 2018 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ:ZLAB), a Shanghai-based innovative biopharmaceutical company, presented results of its open-label study to evaluate the pharmacokinetic (PK) profile of ZL-2306 (niraparib) made in China in Chinese ovarian cancer patients. Results from the study show comparable PK profile of the Chinese patients administered ZL-2306 to that of patients evaluated in Tesaro's global PK study. These data were presented at the 21st Annual Meeting of the Chinese Society of Clinical Oncology (CSCO) on Sept. 21, 2018, at the Xiamen International Conference and Exhibition Center (XICEC) in Xiamen, China.

The open-label PK Study enrolled 36 Chinese patients with stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer. Patients had received no more than two lines of platinum-based therapy and were responsive to the most recent platinum-based treatment. Subjects were randomly assigned to dose levels of 100mg, 200mg and 300mg. The primary objective of the study was to assess the PK profile of ZL-2306 in Chinese patients following both single and multiple doses. The secondary objective was a safety assessment.

The study demonstrated that the drug exposure increased proportionally from 100mg to 300mg, with a T_{max} of approximately three hours. Systemic exposure of ZL-2306, as measured by C_{max} and AUC, increased approximately proportionally with increased dose. The half-life is 31-37 hrs. There were no unexpected safety issues noted during the trial. All key PK and safety parameters were comparable to those in global studies. The study results and population PK data did not identify ethnicity differences between Chinese and non-Chinese patients.

The positive outcome of this PK study will further enhance ZL-2306 application package in China.

About ZL-2306

ZL-2306 (niraparib) is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) PARP 1/2 inhibitor. Niraparib was approved in March 2017 by the FDA in the U.S. and by the EMA in the EU under the trade name ZEJULA® in November 2017 as a maintenance treatment for women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Based on the approval status in the U.S. and EU, Zai Lab submitted a market registration application for niraparib in Hong Kong and plans to launch and commercialize niraparib in Hong Kong in the second half of 2018. Zai Lab believes ZL-2306 has the potential to be a first-in-class Category 1 drug for treatment across multiple solid tumor types in China.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is a Shanghai-based innovative biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. The company's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and addressing unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding business strategy, plans and objectives for future operations and other statements containing words such as "anticipates", "believes", "expects", "plans" and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on Zai Lab's expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) Zai Lab's ability to obtain additional future funding, (2) Zai Lab's results of clinical and pre-clinical development of its drug candidates, (3) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's drug candidates, (4) Zai Lab's ability to generate revenue from its drug candidates, and (5) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2017 and its other filings with the Securities and Exchange Commission. Zai Lab anticipates that subsequent events and developments will cause Zai Lab's expectations and assumptions to change and undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing Zai Lab's views as of any date subsequent to the date of this press release.

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